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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,380	10/13/2005	Per Gisle Djupesland	44508-149	2677

21890 7590 12/11/2007  
PROSKAUER ROSE LLP  
PATENT DEPARTMENT  
1585 BROADWAY  
NEW YORK, NY 10036-8299

EXAMINER
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MATTER, KRISTEN CLARETTE

ART UNIT	PAPER NUMBER
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3771

MAIL DATE	DELIVERY MODE
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12/11/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/520,380

Applicant(s)

DJUPESLAND, PER GISLE

Examiner

Kristen C. Matter

Art Unit

3771

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 25 October 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-25 and 86-90 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7-9, 12-16 and 24 is/are rejected.
- 7) ☒ Claim(s) 6, 10, 11, 17-23, 25 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 10/25/07
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

This Action is in response to the amendment filed on 10/25/2007. Claims 1-5, 7, 10-13, 15, 16, 18-21, and 24 have been amended, claims 26, 52, and 67 have been cancelled, and claims 86-90 have been added. Currently, claims 1-25 and 86-90 are pending in the instant application.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 7, 9, and 12-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Eason et al. (WO 99/58180).

Regarding claims 1 and 2, Eason et al. discloses a nasal delivery device comprising a plurality of disposable (page 3, line 21) interface units attached to a support (Figure 7), each interface unit comprising at least one nosepiece unit for fitting to a respective nostril of a subject and comprising a nozzle (7) from which substance is delivered by at least one delivery unit comprising a substance supply (9), and an actuation unit (29) to which the interface units are successively attached for actuating the at least one delivery unit of each interface unit (see Figure 6). Please note that the various components of Eason et al. can be considered as part of a number of different "units."

Regarding claim 3, each interface unit is a single integral unit (see Figure 8).

Regarding claim 4, Eason et al. discloses the interface units packaged in protective packaging (see Figure 7).

Regarding claim 5, the thin narrow support seen in Figure 7 can be considered a belt.

Regarding claims 12 and 15, the air held in the chamber can be considered a gas supply unit.

Regarding claims 7 and 13, Eason et al. discloses a substance supply unit comprising a pump unit with a cylinder/chamber (21, 45) containing the substance and a piston member (23, 25) moveable in the chamber to deliver a flow of substance from the chamber to a nostril of a user (see Figure 15b).

Regarding claim 9, Eason et al. discloses a powder substance (page 1, first paragraph)

Regarding claims 14 and 16, the "priming" of the pump (page 12, lines 30-35) would initiate some sort of gas flow prior to actuation of the substance supply for delivering the substance.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Eason et al. as applied to claim 1 above, and further in view of Riggs et al. (US 5,355,872). To the extent that Eason et al. is silent as to the substance being liquid, Riggs et al. disclose the equivalence if liquid and powder medicament for use in nebulizers. It would have been obvious to one of ordinary skill in the art at the time of the invention to have used a liquid substance as opposed to a powder substance in the device of Eason et al. depending on what condition was being treated and the needed medicine for therapy.

Claims 24 and 89 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eason et al. as applied to claim 1 above, and further in view of Ohki et al. (US 5,899,202). The difference between Eason et al. and claims 24 and 89 is the interface unit comprising first and second nosepiece units. However, Ohki et al. disclose, in a nasal delivery device, a removable interface unit with first and second nosepieces (27). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to provide Eason et al.'s device with a second nosepiece as taught by Ohki et al. in order to deliver medicament to both nostrils with a single actuation.

Claims 86-90 are rejected under 35 U.S.C. 103(a) as being unpatentable over Curti et al. (US 2006/0174886) in view of Patton et al. (US 6,681,767).

Regarding claims 86 and 89, Curti et al. discloses a delivery device including a nasal cannula with first and second nosepiece units with nozzles (5', 7') and a mouthpiece (9') into which a user exhales (paragraph 0012) and first and second delivery units (210) for delivering a substance supply (abstract and Figure 16C). To the extent that Curti et al. is

silent as to the specifics of the delivery unit and an actuation unit for actuating the delivery unit of the interface unit, Patton et al. discloses a device for delivering a supply to a user comprising a substance supply with a controller for actuating a supply of gas or a fixed amount of liquid propellant to the dispersing device (see column 5, lines 5-15). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used a delivery system as taught by Patton et al. in the device disclosed by Curti et al. for delivering aerosolized medicament to a user. In addition, the interface unit of Curti et al. is said to be "disposable" because it is fully capable of being thrown away (i.e., monitors, gas supplies, cannulas, etc. are able to be disposed of as needed).

Regarding claim 87, the interface unit is a single integral unit (see Figure 11).

Regarding claim 88, although the modified reference does not specifically disclose protective packaging, because the device is replaceable it would have been obvious to one of ordinary skill in the art at the time of the invention to place the molded interfaces in protective packaging until needed because it would have kept the interface sterile while being stored. For extrinsic evidence see Eason et al.

Regarding claim 90, although Curti et al. is silent as to the delivery units being operated in succession, the disclosed device has all of the structural limitations of claim 25 and is fully capable of operating the delivery devices in succession due to the independent flow paths and controller.

***Response to Arguments***

Applicant's arguments with respect to claims 1-25 have been considered but are moot in view of the new ground(s) of rejection.

In response to applicant's arguments regarding the modified Curti et al. device not being disposable as related to claims 86-90, examiner argues that the limitation of being "disposable" merely implies that the device is capable of being thrown away. As discussed above, regardless of what the desired device encompasses (i.e., air cylinders, monitors, etc.), the devices are capable of being disposed of (i.e., if broken for instance) as is the cannula, making the interface unit inherently disposable.

***Allowable Subject Matter***

The indicated allowability of claim 5 is withdrawn in view of the newly discovered reference(s) to Eason et al. Rejections based on the newly cited reference(s) are above.

Claims 6, 10, 11, 17-23, and 25 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristen C. Matter whose telephone number is (571) 272-5270. The examiner can normally be reached on Monday - Friday 9-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Kristen C. Matter  
Examiner  
Art Unit 3771

  
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12/8/07